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Guidance for the Reregistration of Pesticide Products Containing Dimethoate as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING AS THE ACTIVE INGREDIENT

DIMETHOATE
(035001)

CASE NUMBER 0088

CAS 60-15-5

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460

March 1983

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I. INTRODUCTION

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute that product in commerce must apply for reregistration.

This guidance document sets forth the requirements for registration and reregistration of all manufacturing use products (MUPs) containing the subject chemical as the sole active ingredient. These requirements are: that certain scientific data be submitted; that certain standards of toxicity, composition, labeling, and packaging be met; and that the data compensation provisions of FIFRA Section 3(c)(1)(D) be satisfied. Registrants of MUPs are referred to all Sections and Tables for specific information regarding their responsibilities under this guidance document.

This guidance document also sets forth the data requirements and compensation responsibilities for those end-use products which contain the subject active ingredient and for which the source of that active ingredient is (1) not registered with EPA or (2) produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm, or (3) both (1) and (2). Registrants of such end-use products can exempt themselves from these requirements if they change their source of supply to a registered source, provided the source (i.e. registered active ingredient product) is obtained from a firm that does not share ownership in common with the registrant's firm. (If the end-use product registrant decides to switch sources, a new confidential statement of formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this guidance document.) Registrants of affected end-use products are referred to only Sections II, III, IV and VI and Table A for specific information regarding their responsibilities under this guidance document.

It should be noted that end-use products containing the subject active ingredient will not be reregistered at this time. Any necessary labeling changes will be implemented under the Agency's Label Improvement Program at a future time.

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if the registrant fails to comply with the requirements set forth in this guidance document.

This guidance document has been prepared to provide registrants with specific information on how they may reregister their manufacturing-use products or maintain their end-use products' registration. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time frames outlined.

Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

II REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

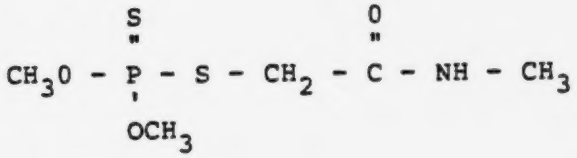
This Registration Standard describes the regulatory position of the Environmental Protection Agency (the Agency) on registered manufacturing-use products (MUPs) containing the insecticide and acaricide dimethoate. The Agency's position is based on an evaluation of all registered uses and registered MUPs with dimethoate as the sole active ingredient. This position is based on a number of considerations. The Standard considers labeling requirements, tolerances, "Special Local Needs" registrations authorized by Section 24(c) of the FIFRA, as well as Federal registrations granted or pending under Section 3 of the FIFRA. Finally, the Agency sets forth the data requirements that must be met to register products covered by this document.

This Standard only addresses registration requirements for current or substantially similar future MUPs and their intermediaries. Dimethoate MUPs that differ appreciably from those described here may require amendments to the Standard. End-use products (EUPs) will be registered under a separate Label Improvement Program.

B. CHEMICAL DESCRIPTION AND USE PROFILE

Dimethoate (Figure 1) is the common name for 0,0-dimethyl S-[N-(methylcarbamoyl)methyl] phosphorodithioate. Dimethoate is also known by the trade names Cygon^{R}, Rogor^{R}, and De-Fend^{R}. The Chemical Abstracts Registry (CAS) number for dimethoate is 60-15-5, the American Cyanamid internal code number is AC-12880, and the EPA Chemical Code number is 035001.

Figure 1



$$CH_3O-\overset{\overset{S}{\|}}{\underset{\underset{OCH_3}{|}}{P}}-S-CH_2-\overset{\overset{O}{\|}}{C}-NH-CH_3$$

Dimethoate is a white crystalline solid with a mercaptan like odor. Its empirical formula is $C_5H_{12}NO_3PS_2$, and its molecular weight is reported to be 229.28. Dimethoate is slightly soluble in water and freely soluble in most organic solvents except saturated hydrocarbons.

There are eleven registered manufacturing-use products consisting of the technical grade of dimethoate, nine of which contain 94-95% dimethoate, one of which contains 82% dimethoate, and one of which contains 38.6% dimethoate; the latter two products are formulation intermediates. There are 57 Federal registered end-use products. In addition, there are 52 "Special Local Needs" registrations.

Dimethoate is a systemic insecticide-acaracide registered as a sole active ingredient and as a mixture with other pesticides for use on a variety of field, vegetable, orchard, forest, and ornamental crops, and for fly control around livestock and poultry facilities, garbage dumps, and commercial, domestic, and recreational establishments.

Dimethoate is formulated into granules (5%), wettable powder (25%), and emulsifiable concentrates (2 to 4 lb/gal and 8 to 30%). Dimethoate is applied by using aircraft and ground spray equipment, including air-blast, knapsack, hydraulic, and other conventional sprayers. The specific type of equipment is determined by site and equipment availability. Applicators need not be certified or under the direct supervision of certified applicators.

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on dimethoate, the Agency has made the following determinations:

1. Available data show that criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations were met or exceeded for some uses of dimethoate.

The Agency published a Rebuttable Presumption Against Registration (RPAR) notice in the Federal Register of September 12, 1977 [42 FR 45086) for all pesticide products containing dimethoate, thereby initiating the Agency's public review of the risks and benefits of dimethoate. The RPAR notice cited three risk criteria which dimethoate had met or exceeded. These three risk criteria were oncogenic effects in test animals [40 CFR 162.11 (a)(3)(ii)(A)), mutagenic effects (multi-test evidence) (40 CFR 162.11(a)(3)(ii)(A)), and reproductive and fetotoxic effects in test animals (40 CFR 162.11(a)(3)(ii)(B)). A detailed Position Document (PD) 1 accompanied the September 12, 1977 notice.

The Agency issued a preliminary Notice of Determination concluding the Rebuttable Presumption Against Registration of Pesticide Products containing Dimethoate and announced the availability of Position Document 2/3 in the Federal Register of November 19, 1979 (44 FR 665580). In Position Document 2/3, the Agency analyzed the rebuttals it received in response to the original RPAR notice, presented its analysis of both risks and benefits associated with the uses of dimethoate, and proposed a decision to conclude the RPAR process.

The Agency determined, in PD 2/3, that the information submitted to rebut the risk criteria for oncogenicity, mutagenicity, and reproductive and fetotoxic effects was insufficient to overcome the presumption against dimethoate for these effects. In addition the Agency received new teratogenic data, unavailable when PD 1 was issued, indicating that dimethoate posed a potential teratogenic hazard. This new information was presented and evaluated in PD 2/3 and the Agency concluded in PD 2/3 that teratogenicity was an additional risk of concern for dimethoate.

In the Preliminary Notice of Determination, the Agency determined that the risks arising from certain uses of dimethoate are greater than the benefits of those uses, unless risks are reduced by modifying certain terms and conditions of registration. The Agency determined that these modifications would significantly reduce risk without significantly impacting on the benefits of the uses.

The modifications to the terms and conditions of registration of dimethoate products proposed by the Agency in the Preliminary Notice of Determination included:

- Cancellation of dust formulations.
- Label changes to require the use of protective clothing and respirators.
- Label changes to require automatic flagging for aerial application.
- Label changes to prohibit air blast application on citrus, pome fruits, and pecans.
- Label changes to include a warning to female workers using air blast equipment of the potential teratogenic effects of dimethoate.

In addition, the Agency determined that registrants would be required to submit data in the areas of oncogenicity, mutagenicity, delayed neurotoxicity, and applicator exposure pursuant to FIFRA section 3(c)(2)(B).

FIFRA requires the Agency to submit notices issued pursuant to section 6 to the Secretary of Agriculture for comment and to provide the Secretary of Agriculture with an analysis of the impact of the proposed action on the agriculture economy under section 6(b). The statute also requires the Administrator to submit notices issued pursuant to section 6 to a Scientific Advisory Panel (SAP) for comment on the impact of the proposed action on health and the environment, at the same time and under the same procedures as those described for review by the Secretary of Agriculture under section 25(d).

After reviewing comments from the Secretary of Agriculture, the Scientific Advisory Panel, and others who commented on EPA's findings and recommendations concerning dimethoate as set forth in PD 2/3, the Agency decided to implement the Proposed Regulatory Option as put forward in PD 2/3 with the following modifications:

- The Agency would not cancel the air blast application of dimethoate on citrus, pome fruits, and pecans. However, the Agency would require an exposure study of dimethoate applicators using contemporary air blast equipment to allow a better assessment than is currently available of the applicators' potential risk for dimethoate in air blast use situations. After the results from the exposure studies become available, the Agency will reevaluate air blast application of dimethoate.

- The Agency would not require a label change to require automatic flagging. Instead the following label statement would be required on all products intended for aerial application:

  > Automatic flagging devices should be used whenever feasible.
  >
  > If Human Flaggers are employed they must wear the protective clothing and respirator specified on this label.

  In addition, the Agency would review an exposure study of flaggers wearing protective clothing during the aerial application of dimethoate to allow a better assessment of the flaggers' potential risk from dimethoate in the aerial use situation.

- The Agency would exempt pilots from the protective clothing and equipment requirement when flying the aircraft.

- The Agency would not require the label warning statement for female applicators. However, the Agency would require additional teratology studies on technical dimethoate.

The Agency's final determination for dimethoate was:

(1) Unconditional denial of all applications for registration of dimethoate products for use in dust formulations.

(2) Cancellation and denial of registrations of dimethoate products for all uses, unless the registrants or applicants for registration modify the labeling of dimethoate products to include the following:

Required Clothing and Equipment for Application. All applicators, including homeowners and flaggers, and personnel involved with the mixing, loading, and transferring operations, must wear the protective clothing and equipment enumerated below. Pilots are exempt from this requirement. The protective clothing and equipment to be worn is as follows:

a. Impermeable gloves (for example, rubber or plastic covered gloves).

b. Rubber or synthetic rubber boots or boot covers.

c. Long-sleeved shirt and long pants made of closely woven fabric.

d. Wide-brimmed hat.

e. Respirators must be worn by flaggers and mixer/loaders.

(3) Cancellation and denial of registration of dimethoate products labeled for aerial application unless the registrants or applicants for registration modify the terms and conditions of registration to include the following statements:

AUTOMATIC FLAGGING DEVICES SHOULD BE USED WHENEVER FEASIBLE. IF HUMAN FLAGGERS ARE EMPLOYED THEY MUST WEAR THE PROTECTIVE CLOTHING AND RESPIRATOR SPECIFIED ON THIS LABEL.

The Agency determined that it would request additional data, under the authority of section 3(c)(2)(B), to maintain the registrations of dimethoate products in effect.

The additional studies which the Agency required are summarized below:

a. A dimethoate oncogenicity study using the same strains of mice and rats used by Gibel *et al*., 1973 (000075634). Later, in negotiations with registrants, the Agency determined that the mouse strain used by Gibel is not available outside of East Germany; therefore, the requirement has been modified to allow the use of any mouse strain susceptible to the type of tumors observed by Gibel.

b. Mutagenicity tests, including gene mutation studies in mammalian systems, a dominant lethal study in mice and studies designed to detect spindle effects, i.e. an *in vivo* bone marrow cytogenetic study.

c. Teratology tests on the technical dimethoate using two species of laboratory animals in accordance with the proposed registration guidelines.

d. Exposure studies to determine worker dermal and inhalation exposure during the application of dimethoate with air blast equipment and dermal and inhalation exposure for flaggers during the aerial application of dimethoate.

Exposure data must be gathered for each crop where air blast equipment is used or on crops deemed representative of such applicator exposure situations.

e. Delayed neurotoxicity tests in accordance with EPA's proposed pesticide registration guidelines.

The Agency's 3(c)(2)(B) letter for dimethoate was issued on November 25, 1981. Since then, the Agency has reconsidered its position on the requirement for delayed neurotoxicity data.

The RPAR PD-1 was critical of one of the neurotoxicity studies (American Cyanamid, 1965; GS0088012) in that only 1/8 of the LD_{50} dose had been administered and because the chemical was administered in the feed. The PD-1 stated that these conditions could compromise adequate dosing. However, the Agency now considers that the repeat administration of a pesticide at lower doses in lieu of single doses near the LD_{50} in a delayed neurotoxicity test is acceptable and is consistent with EPA data standards, especially since the registrant had been unable to obtain protection by the use of atropine in the acute studies. The Agency's previous RPAR determination therefore is set aside regarding delayed neurotoxicity tests.

2. Manufacturing-use pesticide products containing dimethoate as a sole active ingredient may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Standard.

3. Registrants must provide or agree to develop additional data, as specified in the tables attached to this standard, in order to maintain existing registrations or to permit new dimethoate registrations.

4. Tolerance reassessment is normally a part of a Registration Standard review. Although the Agency has reviewed residue data for most commodities and found them mostly adequate, the Agency is unable to complete its reassessment of this compound because major toxicological concerns have not been resolved. When these concerns have been resolved, the Agency will complete its tolerance reassessment, taking into account Delaney Clause restrictions of carcinogens as they concern the dimethoate food additive tolerances. At this time, since the Agency has not concluded that dimethoate is an oncogen or carcinogen, but only that data are suggestive of dimethoate's oncogenicity and that further studies are warranted, then there are no Delaney Clause concerns at this time.

D. REGULATORY RATIONALE

The Agency has determined that it should continue to allow the registration of dimethoate after considering the following:

1. Data from acute oral testing indicates that the acute oral LD50 of dimethoate ranges from 28 mg/kg (Gaines, 1969; 000049330) to greater than 600 mg/kg in male rats.

Generally, the LD50s are in the 150-400 mg/kg range; increased toxicity appears to be associated with impurities.

In acute oral toxicity studies in rats, dimethoate toxicity was additive, but not synergistic, with other pesticides. Dimethoate _per se_ is not irritating to the skin, but it is quite irritating to the eye. No dermal sensitization data are available on dimethoate.

Although requirements for chronic toxicity testing have been partially met, testing results are sufficiently contradictory to necessitate some further testing. Even so, from the available information and from risk assessments made during the RPAR process, no toxicological hazards of concern have been identified at this time that cannot be mitigated by product labeling.

2. Although there are concerns about the chronic toxicological effects of dimethoate, no toxicological evidence or residue chemistry data suggest that current tolerances are likely to result in residue levels that will expose the public to unreasonable adverse effects. (This issue is further discussed in Section H, "Tolerance Reassessment").

3. Available data are insufficient to fully assess the environmental fate of dimethoate. Dimethoate degrades rapidly with a half-life of <3-33 days in aerobic soils under both

laboratory and field conditions. Dimethoate appears to be mobile in coarse- to fine-textured soils; however, its rapid degradation in soil is expected to mediate any potential to contaminate groundwater. [^{14}C]Dimethoate residues (uncharacterized) are taken up by plants. However, dimethoate residues are not expected to persist for a long enough time in soil to be available for uptake by rotational crops. Additional data are needed on photodegradation, hydrolysis, anaerobic soil and water metabolism, leaching, volatility, dissipation and accumulation to confirm these expectations.

4. From available wildlife studies, Agency scientists are able to assess the toxicity of dimethoate to several terrestrial and aquatic test organisms. Dimethoate is highly to very highly toxic to birds in acute doses. Dimethoate is very highly toxic to the stonefly and highly toxic to the scud, both aquatic invertebrates, and moderately toxic to rainbow trout and bluegill sunfish. Studies of toxic effects on beneficial insects show dimethoate to be highly toxic to honey bees, alkali bees, alfalfa leafcutting bees, and to predaceous and parasitic insects, including parasitic wasps, predaceous beetles, mites, flies, and hemipterans.

Non-target organisms can be exposed to dimethoate by residues from direct applications, spray drift from treated areas, and runoff from treated areas. For most uses, such exposure could be acute, repeated, or chronic. Additional information is needed on applications, dosage rates environmental fate and certain non-target organism toxicity data to fully assess wildlife hazard.

5. Available data on human poisoning incidents indicate that the majority of cases cited in the Pesticide Incident Monitoring System through September 1978 (updated through 1981) appeared to be the result of misuse or accident. Potential hazards to farmworkers posed by dimethoate residues in the agricultural workplace are of concern to the Agency. The Department of Food and Agriculture of the State of California has established a safe reentry interval for dimethoate of four (4) days for citrus and grapes. A federal reentry interval has not been established. Registrants may either accept the above reentry intervals (for appropriate crops) or submit data and propose acceptable reentry intervals for each agricultural crop concerned.

6. Under FIFRA the Agency cannot cancel or withhold registration simply because data are missing or inadequate (see Sections 3(c)(2)(B) and 3(c)(7) of the FIFRA). Rather, publication of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registration(s) of dimethoate.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To be covered by this Standard, products must contain dimethoate as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section F of this document.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in it. That includes making a commitment to fill data gaps on a schedule specified by the Agency. Applicants must also indicate a willingness to pay compensation for data to the extent required by Section 3(c)(1)(D) of the FIFRA, as amended, 7 U.S.C. 136(c)(1)(D). Applicants for registration under this Standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be covered under this Standard, manufacturing-use products must contain dimethoate as the sole active ingredient. Each MUP formulation proposed for registration must be fully described with an appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade products and MUPs containing dimethoate for any acute toxicity category, provided that the labeling of those products bear appropriate precautionary statements.

3. Use Patterns

To be registered under this registration standard manufacturing-use products containing dimethoate may be labeled for formulation only into end-use products for:

- Terrestrial non-domestic food uses on: alfalfa, alfalfa (seed only), apples, beans (dry, lima and snap), broccoli, cauliflower, cabbage, celery, cherries, citrus (grapefruit, lemon, orange and tangerine), collards, endive (escarole), kale, lettuce, mustard greens, spinach, Swiss chard, field corn, cotton, grapes, melons, pears, peas, pecans, peppers, potatoes, safflower, sorghum (milo), soybeans, tomatoes, turnips, and wheat.

  Terrestrial domestic food uses on: apples, beans (dry, lima and snap), broccoli, cauliflower, cabbage, celery, cherries, citrus (grapefruit, lemon, orange and tangerine), collards, endive (escarole), kale, lettuce, mustard greens, spinach, Swiss chard, grapes, melons, pears, peas, peppers, pecans, potatoes, tomatoes, and turnips.

- Terrestrial non-domestic non-food uses on: tobacco, non-bearing citrus (trees that will not bear fruit for one year and nursey stock); around homes, recreation areas, animal quarters, food processing plants (including federally inspected meat-packing plants (except where meat and food products are processed or handled), warehouses, loading docks, refuse areas, manure piles, garbage dumps; ornamentals (American holly, English holly, arborvitae, azalea, birch, boxwood, camellia, carnation, cedar, cyperus, daylilies, *Elaeagnus*, elm, *Euonymus*, *Ficus nitida*, gardenia, gerberas (Transvaal daisy), gladiolus, hemlock, iris, juniper, oak, pine, poinsettia, pyracantha, virburnum, rose, taxus (yew), roadsides (24(c) registration), grass grown for seed (24(c) registration), cacti and succulents (24(c) registration), and ferns and foliated potted plants (24(c) registration).

  Terrestrial domestic non-food uses on: ornamentals (as listed above under non-domestic outdoor ornamental uses), and around homes.

- Indoor use in: dairy barns, poultry houses (including poultry droppings in caged-layer houses), hog pens, calf barns and other farm buildings, in federally inspected meat-packing plants (except where meat food products are processed or handled).

- Forestry uses in Douglas-fir, pine, and pinyon pine

End-use products formulated from products registered under this Standard may be granules, wettable powders, or emulsifiable concentrates. As noted earlier, all dust end-use products have been cancelled.

G. Required Labeling

All technical grade, manufacturing-use, and end-use products containing dimethoate must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements.

1. Use Pattern Statements

The ingredients statement for MUPs must list the active ingredient as: Dimethoate: 0,O-dimethyl S-[N- (methylcarbamoyl) methyl] phosphorodithioate-%. In addition, all MUPs must state that they are intended only for formulation into end-use products for any of the use patterns listed in F.3. above, "Use Patterns".

2. Precautionary Statements

Labels for all MUP products containing dimethoate must bear statements reflecting the acute human toxicity of the compound. The guidance package provides an updated list of all precautionary statements which must appear for each type of product.

The following environmental hazard statement must appear on manufacturing-use product labels:

> This pesticide is toxic to wildlife and aquatic invertebrates. Do not discharge into lakes, streams, ponds, or public waters except in accordance with a NPDES permit. For further guidance contact the nearest EPA Regional Office.

Labels of all end-use products containing dimethoate are required to contain the following:

> All applicators, flaggers and all personnel involved with the mixing, loading, and transferring operations must wear the protective clothing and equipment enumerated below. Pilots are exempt from this requirement. The protective clothing and equipment to be worn is as follows:
>
> a. Impermeable gloves (for example. rubber or plastic covered reinforced gloves.)
>
> b. Boots or boot covers.
>
> c. Long-sleeved shirt and long pants.
>
> d. Wide-brimmed hat.
>
> e. Respirators must be worn by flaggers and mixer/ loaders.

The labels of all dimethoate products intended for aerial application must state:

> AUTOMATIC FLAGGING DEVICES
> SHOULD BE USED WHENEVER FEASIBLE.
>
> IF HUMAN FLAGGERS ARE EMPLOYED THEY
> MUST WEAR THE PROTECTIVE CLOTHING
> AND RESPIRATOR SPECIFIED ON THIS LABEL.

The labels of products containing dimethoate intended for homeowner use only may, at the registrants' option, state:

> The following protective clothing must be worn during application:
>
> a. Impermeable gloves (for example: rubber or plastic covered reinforced gloves.)
>
> b. Boots or boot covers.
>
> c. Long-sleeved shirt and long pants.
>
> d. Wide-brimmed hat.

End-use products meant for any applications except pine forests are required to contain the following statement:

> This pesticide is toxic to wildlife and aquatic invertebrates. Do not apply directly to water or wetlands. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning equipment or disposal of wastes.

End-use products for pine forest use are required to contain the following statement:

> This pesticide is toxic to wildlife and aquatic invertebrates. Do not apply directly to water or wetland not under the forest canopy. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning equipment or disposal of wastes.

Granular formulation labels should also contain the statement:

> Cover or incorporate granules that are spilled during loading.

End-use products (except granulars) meant for outdoor use should have the following label statement:

> This pesticide is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

Also, the following auxiliary statements should be placed in the use directions as appropriate:

- Foliar application to alfalfa, peas, or beans: Do not apply if the crop or weeds in the treatment area are in bloom.
- Foliar application to corn: Do not apply to corn during the pollen-shed period.
- Foliar application to listed fruit trees (apple, cherry, citrus): Do not apply when trees or substantial numbers of weeds in the orchard (grove) are in bloom.

Label changes to EUPs are not required by this Standard; however, based on data reviewed by the Agency, certain environmental statements will be required when EUPs are reregistered under the Agency's Label Improvement Program.

The Agency may, after review of data to be submitted under this Standard, impose additional label requirements.

H. Tolerance Reassessment

1. U.S. Tolerances

Table 1 shows U.S. tolerances for dimethoate and its oxygen analog, dimethoxon.

The plant and animal metabolism of dimethoate is well characterized. Dimethoate is readily taken up and translocated by plants, and is metabolized by competing hydrolytic and oxidative processes. The residue of concern in plants is the parent compound and its oxygen analog, dimethoxon. The metabolism of dimethoate in food-producing animals is similar to that in plants and the residues of concern are the same.

U.S. tolerances for most raw agricultural commodities are supported by current residue chemistry data. In some cases, however, either more data or restrictions of use are required:

- Either additional residue data for sorghum grain or pertinent details of the residue studies already submitted, or a restriction against application of dimethoate to sorghum after head formation.
- Either data on residues in cover crops in dimethoate-treated apple, pear, cherry, and citrus orchards, or a restriction against grazing livestock in treated orchards.
- Data on residues in processed apple and tomato products and by-products.

Table 1. U.S. Residue Tolerances for Dimethoate and Its Oxygen Analog

Commodity	Parts per million
Alfalfa	2
Apples	2
Beans (dry, lima, snap)	2
Broccoli	2
Cabbage	2
Cauliflower	2
Celery	2
Collards	2
Endive (escarole)	2
Grapefruit	2
Kale	2
Lemons	2
Lettuce	2
Mustard greens	2
Oranges	2
Pears	2
Peas	2
Peppers	2
Soybeans forage	2
Soybean hay	2
Spinach	2
Swiss chard	2
Tangerines	2
Tomatoes,	2
Turnips (roots and tops)	2
Wheat (green fodder and straw	2
Corn fodder and forage	1
Grapes	1
Melons	1
Potatoes	0.2
Sorghum forage	0.2
Cotton seed	0.1
Pecans	0.1
Safflower seed	0.1
Sorghum grain	0.1
Corn Grain	0.1 (negligible residue)
Soybeans	0.05 " "
Wheat grain	0.04 " "
Eggs	0.02 " "
Meat, Fat and Meat byproducts (cattle, goats, hogs, horses, poultry, and sheep)	0.02 " "
Milk	0.002 " "

- Either data supporting multiple applications of dimethoate to peas, or a label restriction limiting use on peas to 1 application per season.
- Either an increase in the PHI for wheat forage, or a label restriction limiting the number of applications of dimethoate to wheat to two per season.
- Additional residue data for tobacco.

Also, although for many crops there are no data to support aerial application, residues from this mode of application are unlikely to exceed those from ground application provided that label directions concerning spray volumes are followed. Therefore, additional data for aerial application are not required.

The Acceptable Daily Intake (ADI) is 0.0200 mg/kg/day, and is based on the human cholinesterase inhibition NOEL of 0.200 mg/kg/day (established by subchronic daily dosing) and a safety factor of 10. The Maximum Permissible Daily Intake (MPI) is 1.200 mg/day (based on a 60 kg body weight person). The Theoretical Maximum Residue Contribution (TMRC), based on the relevant food factors and published food tolerances is 0.5150 mg/day, assuming a 1.5 kg diet. The required residue tolerances utilized 42.92% of the ADI. Therefore, the established tolerances are acceptable and adequate in light of the human data on which they were based. Although there are concerns about the chronic toxicological effects of dimethoate (and these are the subjects of additional tests being planned and conducted), no existing evidence suggests that current tolerances are likely to result in residue levels that will expose the public to unreasonable adverse effects. The ADI will be reevaluated after review of the requested data.

A correction to the dimethoate tolerances is:

- 40 CFR 180.204. The tolerance for residues on alfalfa should be expressed in terms of "alfalfa, fresh" and "alfalfa, hay" rather than "alfalfa".

In addition, pesticide registrants should petition the Agency to establish or amend the following tolerances:

- 21 CFR 561.170. The magnitude of the tolerance for dried citrus pulp should be increased from 5 ppm to 10 ppm.
- A tolerance of 7 ppm for combined residues of dimethoate and dimethoxon in citrus oil should be established under 21 CFR, Part 193.

2. International Tolerances.

Table 2 compares U.S. tolerances for residues of dimethoate with recommended Codex Maximum Residue Limits (MRL's), and with tolerances established by Mexico and Canada. There are no Codex, Mexican, or Canadian tolerances for the following commodities with U.S. tolerances: meat, milk, poultry, eggs, collards, cottonseed, endive, mustard greens, and turnip roots.

The residue definition is the same for the U.S., Codex, and Canada, i.e., the parent compound and its oxygen analog, dimethoxon (omethoate). It is not clear whether the Mexican residue definition includes the analog.

The U.S. tolerances for residues of dimethoate listed in 40 CFR 180.204 provide for the use of dimethoate only, whereas the Codex MRL's provide not only for the use of dimethoate, but for the use of the pesticide formothion, of which dimethoate and dimethoxon are metabolites; and for the purposeful use of dimethoxon. This situation results in an enforcement problem for the U.S. because the U.S. Food and Drug Administration has taken the position that residues resulting from the purposeful use of a pesticide for which there is no U.S. tolerance are actionable. Thus, the residues resulting from the use of formothion or dimethoxon on a particular commodity would be considered violative even if the magnitude of the residues were within the U.S. tolerance for residues of dimethoate and dimethoxon on the commodity.

Table 2. United States Codex, Mexican, and Canadian Tolerances for Dimethoate.

	U.S.	CODEX	MEXICO	CANADA
Alfalfa	2.	-	2	-
Apples	2.	2.	2.	2.
Apricots	-	2	-	-
Avocado	-	-	0.5	-
Beans (succulent/dried	2.	-	2.	1.
Beet greens	-	-	-	2.
Broccoli	2.	-	2.	2.
Cabbage	2.	-	-	2.
Cauliflower	2.	-	-	2.
Celery	2.	-	2	1.
Cherries	2.	2	-	1.
Citrus Fruits	2.	2*	2.	1.5
Corn forage/fodder	1.	-	1.	-
Corn grain	0.1 (N)	-	1. (N)	0.1 (N)
Currants, black	-	2*	-	-
Grapes	1.	2.	1.	-
Hops (dried)	-	3.	-	-
Kale	2.	-	-	2.
Lettuce	2.	-	2.	2.
Melons	1.	-	1.	-
Olives	-	2.	-	-
Peaches	-	2.	-	-
Pears	2.	2.	2.	2.
Peas	2.	-	2.	0.5
Pecans	0.1	-	0.05	-
Peppers	2.	1.*	2. (chili)	0.5
Plums	-	2.	-	-
Potatoes	0.2	0.05	0.2	-
Safflower seed	0.1	-	0.05	-
Sorghum forage	0.2	-	0.2	-
Sorghum grain	0.1	-	0.05	-
Soybeans	0.05 (N)	-	0.05	-
Soybean forage/hay	2.	-	2.	-
Spinach	2.	-	2.	2.
Strawberries	-	1.*	-	1.
Sugarbeet roots	-	0.05	-	-
Sugarbeet tops	-	1.	-	-
Swiss chard	2.	-	-	2.
Tomatoes	2.	1.*	-	0.5
Turnip Tops	2.	-	-	2.
Vegetables	-	2.*	-	-
Wheat Forage/straw	2.	-	2.	-
Wheat grain	0.04 (N)	-	0.04 (N)	-

*Temporary Maximum Residue Limits (MRL's). All other MRL's are at step 7 in the procedure for the elaboration of Codex Maximum Limits for pesticide residues.
(N): Negligible residue

Codex MRL's are lower than corresponding U.S. tolerances for residues on peppers, potatoes, and tomatoes, and higher for grapes. If the codex MRL for grapes is toxicologically supportable, and the U.S. tolerance subsequently raised to match the MRL, the TMRC would increase by 0.007 mg per day.

III. DATA COMPENSATION

As part of your application for reregistration, you must comply with the data requirements of FIFRA Section 3(c)(1)(D) by including with your application a completed Data Compensation Statement (Appendix III-1). That form includes:

A. A statement that you offer to pay compensation to other persons with regard to the application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D).

B. A statement acknowledging that if EPA approves your application for registration, the approval will be based on EPA's consideration of the following:

1. All the existing "generic" data* which, according to the table, "Generic Data Requirements for Manufacturing Use and End Use Products" (Table A at the end of Section IV), is relevant to EPA's evaluation of the registrability of your product.

2. For the manufacturing use products, the "product-specific" data* which you have listed on the form entitled "Product-Specific Data Report" (Appendix III-2).

C. A statement that you have furnished an offer to pay compensation to the person(s) listed below in the manner specified:

1. Persons to whom offers must be made: An offer must be furnished to each person who was the original submitter of any of the generic or product specific data upon which approval of your application will be based, except that:

   a. You need not furnish an offer with respect to data that were originally submitted prior to January 1, 1970.

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*/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

b. Many data submitters have informed EPA that they do not wish to receive offers under FIFRA Section 3(c)(1)(D). The various persons who submitted data listed in the bibliography (Appendix III-3) who have not waived their rights to receive offers will be listed in Tables A and B (MUP registrants are referred to both Tables A & B; end-use product registrants are referred to only Table A). You will be required to write the companies listed in the appropriate table(s) if the data in those tables are required to support your formulations and/or uses.

c. You need not furnish an offer to any person with whom you have already agreed in writing concerning the amount (if any) and terms of compensation payable under FIFRA Section 3(c)(1)(D) in connection with the reregistration of your product.

d. You need not furnish an offer with respect to any data unless the data were submitted to EPA (or its predecessor agencies) to support an application for registration, amended registration, or reregistration; to support or maintain in effect an existing registration; to support an application for an experimental use permit; or to support a petition for a tolerance, food additive regulation, or other clearance under the Federal Food, Drug and Cosmetic Act which was a prerequisite to a FIFRA registration action.

2. Form of the offer: You must furnish each person who is entitled to receive an offer the following information, in writing:

   a. A notification of your intent to apply for registration or reregistration under this guidance document, and the name, active ingredient, and intended uses of your product.

   b. An offer to pay the person compensation with respect to approval of your application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D), and an offer to begin negotiations to set the amount and terms of compensation.

   c. Your name, mailing address, and telephone number.

IV. REQUIREMENT FOR SUBMISSION OF GENERIC DATA UNDER FIFRA SECTION 3(c)(2)(B)

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B). EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, The Pesticide Registration Guidelines,*/ or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally Ecological Effects), EPA requires the test substance to be a "typical formulation," and that in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.). These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Section V of this document.

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*/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

C. Options Available for Complying with Requirements to Submit Data.

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA § 3(c)(2)(B) Summary Sheet" [Appendix IV-2(a)] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" (Appendix IV-3*/.

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement between all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing. (Footnote continued on next page.)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Continued)
As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)], and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

Table ..

GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?4/
Section 158.120 Product Chemistry				
Product Identity:				
61-2 - Statement of Composition	TGAI	Partial1/	000075600 [241-218](a) 000071499 [4787-7](b) 000075618 [33660-12]	Yes
61-3 - Discussion of Formation of Impurities	TGAI	Partial2/	000071499 [4787-7](b)	Yes
		Partial3/	000075657 [241-218](a) 000075658 [241-218](a) 000075652 [241-218](a)	Yes
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	TGAI	Partial2/	000083039 [4787-7](b) 000071503 [4787-7](b)	Yes

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1/ Manufacturing process data need not be submitted for registrations 241-218, 4787-7, and 33660-12. A description of beginning materials is required for all products.

2/ Satisfactory data have been submitted for the products indicated. Data must be submitted for all other products.

3/ The methylamide group of dimethoate is nitrosatable, and nitrosamines may form on storage is nitrosating agents are present in the packaging materials. Satisfactory data have been submitted for the indicated products that nitrates and nitrites are not present in their containers. All registrants should submit evidence that their product containers are free of nitrosating agents.

4/ All data must be submitted within 6 months (due 9/30/83).

Table A

GENERIC DATA REQ[illegible]NTS FOR DIMETHOATE

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?
Section 158.120 Product Chemistry				
Physical and Chemical Characteristics:				
63-2 - Color	TGAI	Yes	000071505(b) 000075618 000077481(a) 000075612(c) 000075570(d)	No
63-3 - Physical state	TGAI	Yes	000071505(b) 000075618 000077481(a) 000075612(c) 000075570(d)	No
63-4 - Odor	TGAI	Yes	000071505(b) 000075618 000077481(a) 000075612(c)	No
63-5 - Melting point	TGAI	Yes	000075618 000077481(a) 000075570(d) 000071505(b) 000075612(c)	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	000071505(b) 000075618 000077481(a)	No

Tab

GENERIC DATA REQUI S FOR DIMETHOATE

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[2]
Section 158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI or PAI	Yes	000071505(b) 000075612(c) 000075570(d) 005014774 000077481(a)	No
63-9 - Vapor pressure	PAI	Yes	000071505(b) 000077481(a) 000075570(d)	No
63-11- Octanol/water partition coefficient	PAI	Yes	000071505(b) 005014774	No
63-12- pH	TGAI	Partial[1]	000071505 [4787-7](b) 000075612 [2749-46](c)	Yes
63-13- Stability	TGAI	Yes	000071505(b) 000077481(a) 000075612(c) 000075570(d)	No

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[1] Satisfactory data have been submitted for the product(s) indicated. Data must be submitted for all other products.

[2] All data must be submitted within 6 months (due 9/30/83).

Table A
GENERIC DATA REQUIREME OR DIMETHOATE

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?
Section 158.120 Product Chemistry (continued)				
Other Requirements:				
64-1 - Submittal of Samples	Reserved[1]			

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[1] The Agency will require a sample later if need arises.

Table A
GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirements	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?
Section 158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Yes	GS0088009 000052096(a) 000052088(a) GS0088008 000052102(a) 000075584(a) 000075665(a) GS0088007 000077548(a) GS0088011	No

Table ( )

GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirements	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?
Section 158.125 Residue Chemistry (Continued)				
171-4 - Nature of Residue (Metabolism) - Livestock	PAIRA and plant metabolites	Yes	000077525(a) 000077511 000077514 000077512 000051683(a) 000051682(a)	No
171-4 - Residue Analytical Method	PAI and Analytically Pure Dimethoxon	Yes	000051669 000075619(a) 000075607(a) 000051670(a) 000077547(a) GS0088010 GS0088006	No
171-4 - Storage Stability Data	Residue-bearing commodities and PAI-spiked samples	Yes	000075578(a) 000075553(a) 000077548(a)	No

Data Requirements	Composition	Does ve Data to Sa This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[4]
Section 158.125 Residue Chemistry (Continued)				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Brassica Leafy Vegetables				
Broccoli	TEP	Yes[1]	000077551(a)	No
Cabbage	TEP	Yes[1]	000077551(a)	No
Cauliflower	TEP	Yes[1]	000077551(a)	No
Collards	TEP	Yes	000077552(a)	No
Kale	TEP	Yes	000077552(a) GS0088011	No
Mustard greens	TEP	Yes	000077552(a)	No
Cereal Grains				
Field corn	TEP	Yes	000050742	No
Sorghum	TEP	Partial[2]	000075549(a)	Yes
Wheat	TEP	Yes	000075540(a) 000075662(a)	No
Citrus Fruits				
Grapefruit	TEP	Partial[3]	000077499(a)	Yes
Lemons	TEP	Partial[3]	000073441(a)	Yes
Oranges	TEP	Partial[3]	000073441(a)	Yes
Tangerines	TEP	Partial[3]	000077499(a)	Yes
Cottonseed	TEP	Yes	000075601(a)	No

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[1] For these uses, labeling must require a PHI of 7 days.

[2] Additional residue data or details of the original residue studies for sorghum grain are required. Alternatively a label restriction against application of dimethoate after heading would be acceptable.

[3] Either residue data for cover crops grown in treated orchards or a label restriction against grazing livestock in treated orchards will be necessary.

[4] All data must be submitted within 36 months (due 4/86).

Table A

GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirements	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?
Section 158.125 Residue Chemistry (Continued)				
Foliage of Legume Vegetables				
Soybeans	TEP	Yes	000075577(a)	No
Forage, Fodder, and Straw of Cereal grains				
Field Corn	TEP	Yes	000075594(a) 000050742	No
Sorghum	TEP	Yes	000075549(a)	No
Wheat	TEP	Yes1/	000075540(a) 000075662(a)	No
Fruiting Vegetables (Cucurbits)				
Melons	TEP	Yes	000075529(a)	No
Fruiting Vegetables (Except Cucurbits)				
Peppers	TEP	Yes	000077549(a)	No
Tomatoes	TEP	Yes	000077550(a)	No

1/ However, either an increase in the PreHarvest Interval (PHI) for wheat forage, or a label restriction limiting the number of applications of dimethoate to wheat to two per season is required.

Table A

GENERIC DATA REQUIREM FOR DIMETHOATE

Data Requirements	Composition	Does EP. ve Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[2]
Section 158.125 Residue Chemistry (Continued)				
Leafy Vegetables (Except Brassica Vegetables)				
Celery	TEP	Yes	000075665(a)	No
Endive/Escarole	TEP	Yes	000077552(a)	No
Head Lettuce	TEP	Yes	000077552(a)	No
Leaf Lettuce	TEP	Yes	000077552(a)	No
Spinach	TEP	Yes	000077552(a)	No
Swiss Chard	TEP	Yes	000077552(a)	No
Leaves of Root and Tuber Vegetables				
Turnips, Tops	TEP	Yes	000077552(a)	No
Legume Vegetables (Succulent or Dried)				
Beans	TEP	Yes	000075607(a) 000075560	No
Peas	TEP	Partial[1]	000075624(a) 000075554(a)	Yes
Soybeans	TEP	Yes	000075577(a)	No
Non-Grass Animal Feeds				
Alfalfa	TEP	Yes	000075584(a) 000075659(a)	No

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[1] Data supporting multiple application of dimethoate to peas, or a restriction limiting use of dimethoate on peas to 1 application per season are required.

[2] All data must be submitted within 36 months (due 4/86).

GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirements	Composition	Does E a Data to Sat his Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[3/]
Section 158.125 Residue Chemistry (Continued)				
Pome Fruits Apples	TEP	Partial[1/]	000077548(a) 000051669(a) 000051684(a) 000075557(a)	Yes
Pears	TEP	Partial[1/]	000077548(a) 000051685(a)	Yes
Root and Tuber Vegetables				
Potatoes	TEP	Yes	000034364(a)	No
Turnips	TEP	Yes	000075552(a)	No
Safflower seed	TEP	Yes	000075601(a)	No
Small Fruits and Berries Grapes	TEP	Yes	000075590(a) 000075531(a) 000077471(e)	No
Stone Fruits Cherries	TEP	Partial[2/]	Pesticide Petition 7E1949	Yes
Tree Nuts Pecans	TEP	Yes	000077484(a)	No

[1/] Either residue data for cover crops grown in treated orchards or a label restriction against grazing livestock in treated orchards will be necessary.

[2/] These data were generated in Oregon. For dimethoate to be used on cherries in other states under current 24(c) registrations, additional data may be required.

[3/] All data must be submitted within 36 months (due 4/86).

Table A

GENERIC DATA REQUIR FOR DIMETHOATE

Data Requirements	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[4]
Section 158.125 Residue Chemistry (continued)				
Residues in Tobacco	TEP	Partial[1]	000045838(a)	Yes
Residues in Processed Commodities	Residue-bearing Raw Agricultural Commodities			
Apples	"	No		Yes
Citrus fruits		Yes	000075580(a) 000073441(a) GS0088007	No
Corn	"	No		No[2]
Cottonseed		No		No[2]
Grapes		Yes	000075590(a) 000075637(a)	No
Potatoes	"	No		No[2]
Safflower seed		No		No[2]
Sorghum		No		Yes[3]
Soybeans		No		No[2]
Tomatoes		No		Yes
Wheat		No		No[2]

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[1] Data for residues of dimethoxon on tobacco are required. If combined residues of dimethoate and dimethoxon exceed 0.1 ppm on green tobacco, data for air- and flue- cured tabacco will be required; and if combined residues on cured tobacco exceed 0.1 ppm, than a residue profile of tabacco smoke will be required.

[2] Because there are no residues detected in the raw agricultural commodity, a processing study is not required.

[3] If detectable residues occur on sorghum grain (see footnote 2/), a processing study will be necessary.

[4] All data must be submitted within 36 months (due 4/86).

Table A
GENERIC DATA REQUIREM[illegible] FOR DIMETHOATE

Data Requirements	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?
Section 158.125 Residue Chemistry (continued)				
Residues in Food-Producing Animals				
Meat				
-feed use	TGAI	Yes	000077543(a) 000073444(a)	No
-premise use	TEP	Yes	000077494(a)	No
Milk				
-feed use	TGAI	Yes	000073444(a)	No
-premise use	TEP	Yes	000077501(a)	No
Poultry				
-feed use	TGAI	Yes	000077495(a)	No
-premise use	TEP	Yes	000077495(a)	No
Eggs				
-feed use	TGAI	Yes	000077495(a)	No
-premise use	TEP	Yes	000077495(a)	No

Table A
GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?
Section 158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD50 - Rat	TGAI	A,B,G,H,I	Yes	000055377(d); 000051674(a); 000055371(d); 000049330; 000073757(f); 000073440(a); 000037597; 000044988(a); 000043996; 000071569(b); 000071504(b); 000051677(a); 000044982(a)	No
81-2 - Dermal LD50	TGAI	A,B,G,H,I	Yes	000051674(a); 000049330	No
81-3 - Inhalation LC50 - Rat	TGAI	A,B,G,H,I	Yes	000060719(f)	No
81-7 - Acute Delayed Neurotoxicity	TGAI	A,B,G,H,I	Yes	000051679(d) 000045817(a) 000049330	No[1]

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[1] These data were originally required in accordance with the terms of the Position Document 4 which concluded the Rebuttable Presumption Against Registration (RPAR) of dimethoate and in accordance with the 3(c)(2)(B) letter (also called Data Call-In Notice) on dimethoate of 11/25/81. After a re-examination of the data reviewed for the RPAR, the Agency has determined that these data show that dimethoate does not cause delayed neurotoxicity in test animals.

Table

GENERIC DATA REQUI S FOR DIMETHOATE

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[4]
Section 158.135 Toxicology (Continued)					
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Nonrodent	TGAI	A,I	Yes	000051676(a); 000075532(a); 00051675(a); 000055374(a)	No
82-2 - 21-Day Dermal	TGAI	A,B,G,H,I	No	-	Yes
82-3 - 90-Day Dermal	-	-	No	-	No[1]
82-4 - 90-Day Inhalation - Rat	Reserved[2]	B	No	-	
82-5 - 90-Day Neurotoxicity-	TGAI	A,B,G,H,I	No	-	No[3]
Hen					
Mammal					

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[1] The 90-Day Dermal Toxicity Test is not required because dimethoate's pesticidal uses exclude swimming pools and fabrics and do not involve intentional application to the skin.

[2] A test with duration of 21 days may be required if a pesticide is used on tobacco; dimethoate is used on tobacco, but the extent of residues of dimethoate and its oxygen analog on tobacco are not known. These data have been requested (Section 158.125). After reviewing those requested data, the Agency will determine if the 21-day Inhalation Toxicity Study is required.

[3] These data are not required because delayed neurotoxicity tests do not show neuropathy or neurotoxicity.

[4] All data must be submitted within 36 months (due 4/86).

Table

GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?
Section 158.135 Toxicology (Continued)					
CHRONIC TESTING					
83-1 - Chronic Toxicity - 2 ssp. Rodent and Non-rodent	TGAI	A,B,G,H,I	Partial1/	000063995(a)	Yes
83-2 - Oncogenicity Study - 2 ssp. Rat and mouse preferred	TGAI	A,B,G,H,I	Partial2/	000063997 000075634(a)	Yes
83-3 - Teratogenicity - 2 species	TGAI	A,B,G,H,I	Partial3/	005018751	Yes
83-4 - Reproduction, 2-Generation	TGAI	A,B,G,H,I	Yes	000045816	No

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1/ A complete chronic toxicity study is needed in the rat (2-year feeding). A chronic feeding study is waived in the dog because 2 subchronic dog studies and the human studies show similar toxicity. Because there are human data, the Agency does not believe another dog study would contribute any meaningful data to the data base. This study is to be completed by 11/85 in accordance with the 3(c)(2)(B) letter (also called Data Call In Notice) of November 25, 1981.

2/ Another oncognicity study is requested using the Wistar rat and a mouse strain susceptible to the type of tumor found in the Gibel oncogenicity study. This study is to be completed by 11/84 to satisfy the terms of the Position Document 4 which concluded the Dimethoate RPAR, and the terms of the 3(c)(2)(B) letter.

3/ These studies were conducted with a 47.3% formulation; they should be repeated using the TGAI. These studies are to be completed by 5/83 to satify the terms of the Position Document 4 and the 3(c)0(2)(B) letter (or Data Call-In Notice).

Table A
GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?
Section 158.135 Toxicology (Continued)					
MUTAGENICITY TESTING:					
84-2 - Gene Mutation 84-2 - Chromosomal Aberration 84-4 - Other Mechanisms of Mutagenicity	TGAI	A,B,G,H,I	Partially	000063996(a) 005012445 005022182	Yes[1/]
SPECIAL TESTING					
85-1 - General Metabolism	PAIRA	A,B,G,H,I	Yes	000051682(a); 000044983(a)	No

[1/] Three studies or sets of studies were required to satisfy the terms of the Position Document 4 and the 3(c)(2)(B) letter (or Data Call In Notice): gene mutation studies in mammalian systems, a dominant lethal study in mice, and studies to detect spindle effects. Currently, there are not sufficient data upon which to base a mutagenic risk assesment for dimethoate. Several of these studies have been received by the Agency and are being reviewed; this group of studies is to be completed by 5/83]. Until the receipt and review of the studies to be submitted regarding the Position Document 4 and the 3(c)(2)(B) letter, the guideline requirements for mutagenicity studies are reserved.

Table A
GENERIC DATA REQUIREME R DIMETHOATE

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[2/]
Section 158.130 Environmental Fate					
DEGRADATION STUDIES - LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,G,H,I	No	-	Yes
161-2 - Photodegradation In water	TGAI or PAIRA	A,B,G,H,I	No	-	Yes
161-3 - On Soil	TGAI or PAIRA	A,G	No	-	Yes
161-4 - In Air	Reserved[1/]				
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,G,H	Yes	000052099(a) 000052091(a)	No
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes
162-3 - Anaerobic Aquatic	TGAI or PAIRA	G	No	-	Yes

1/ These data are required on a case-by-case basis to support the registration of a product that demonstrates a high potential for volatization and is intended for terrestrial food crop use involving a potentially significant exposure to workers. Whether these data will be required will be decided upon review of data from Sec. 163.2 (volatility).

2/ All data must be submitted within 36 months (due 4/86).

Table A
GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?
Section 158.130 - Environmental Fate (continued)					
MOBILITY STUDIES :					
161-1 - Leaching (Absorption/ Desorption	TGAI or PAIRA	A,B,G,H,I	No	-	Yes[1]
161-2 - Volatility (lab)	TEP	A	No	-	Yes
161-3 - (Field)	TEP	A,G	No	-	Yes
DISSIPATION STUDIES - Field:					
164.1 - Soil	TEP	A,B,H	Partial	000033896(a) 000052085(a)	Yes[2]

1/ The columns used in studies reviewed were too short to fully assess the mobility of dimethoate in soils.

2/ These studies provided data on dissipation of on emulsifiable concentrate formulation in sandy loam. Dissipation studies must be made on one other site representative of the area where dimethoate is to be used and data are required for a granular or wettable powder formulation.

Table A
GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[2]
158.130 Environmental Fate (continued)					
164-3 - Forestry	TEP	G	No	-	Yes
164-5 - Soil, Long-term	TEP	A,B,G,H,I	No	-	No[1]
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	No	-	No[1]
165-2 - Rotational Crops (Field)	TEP	A	No	-	No[1]

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[1] These data are not required because data submitted for Sec. 162-1 indicate that dimethoate dissipates in aerobic soil with a half-life <15 days.

[2] All data must be submitted within 36 months (due 4/86).

TABLE A

GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must ional Data ubmitted under FIFRA Section 3(c)(2)(B)?3/
158.130 Environmental Fate (continued)					
165-4 - In Fish	TGAI or PAIRA	A,B,G	No	-	No1/
165-5 - In Aquatic Non-Target Organisms	TEP	G	No	-	Yes2/

1/ Fish accumulation data will not normally be required in situations where the registrant can offer acceptable evidence showing that the active ingredient and/or its principal degradation product(s):

- o Will not reach water, or
- o Will not persist in water (i.e., a half-life of 4 days or less) and has properties suggesting:
  - A relatively low potential for accumulation in fish (i.e., an octanol/water partition coefficient less than 1,000) or
  - A lack of accumulation in the organs and tissues of mammals or birds.

No data are available on the accumulation of dimethoate in fish under laboratory conditions. However, the octanol/water partition coefficient is much less than 1000 and these data are therefore not required.

2/ Field accumulation studies in aquatic non-target organisms are required to support the registration of each end-use product:

- o Which is intended for forestry use, aquatic non-crop use, or aquatic impact use that results in direct discharges;
- o For which data from a laboratory fish accumulation study are required by Section 163.165-4; and
- o for which no tolerance or action level for fish has been granted.

Such studies are also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

No data are available on the accumulation of dimethoate in aquatic non-target organisms.

3/ All data must be submitted within 36 months (due 4/86).

Table A
GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[6]
158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Single-Dose Oral LD50	TGAI, dimethoxon[5]	A,B,G,H,I	Yes	GS0088003 000020560 GS0088002	No
71-2 - Avian Dietary LC50	TGAI, dimethoxon[5]	A,B,G,H,I	Yes	000022923	No[1]
71-4 - Avian Reproduction	TGAI, dimethoxon[5]	A,B,G,H	No	-	Yes[2]
71-5 - Simulated and Actual Field Testing - Mammals and Birds	(Unique formulation) Reserved		Partial[4]	000075585(a) 000075575(a)	No[3]

1/ For Use Pattern I, Indoor Use, data to be cited is that with the ring-necked pheasant.

2/ Based on existing labeling, uses requiring these studies to fully evaluate potential hazard include field corn, wheat, alfalfa, citrus, sorghum, soybeans, tomatoes, cotton, apples grapes, pears, and pine forest (individually and/or collectively) due, in part, to the potential for repeated or continuous avian exposure to dimethoate or its metabolite dimethoxon over an extensive acreage. Testing should be performed on the bobwhite quail and mallard using technical dimethoate.

3/ Depending on the full extent of repeat applications, outstanding environmental fate data, clarification of application rates where not cited on existing labels, and/or results of avian reproduction studies, one or more of these studies may be required for hazard evaluation.

4/ The field study and separate necropsy report cited are acceptable for hazard evaluation on a case-by-case basis should field studies be required for hazard evaluation.

5/ Pending the result of environmental fate field studies, a study on dimethoxon may be required.

6/ All data must be submitted within 36 months (due 4/86).

Table A
GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[5]
158.145 Wildlife and Aquatic Organisms					
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC50	1) TGAI, dimethoxon[4]	A,B,G,H,I	1) Yes	1) GS0088013 GS0088004 GS0088001	1) No[1]
	2) (Unique[2] formulation)		2) Partial[3]	2) 000077504	2) Yes

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[1] For Use Pattern I, Indoor Use, data to be cited is that with the rainbow trout.

[2] The emulsifiable concentrate formulation used on pine forests is to be tested.

[3] While the cited study is considered scientifically sound, it cannot be upgraded to fully meet the intent of Subdivision E (10/1982) because the test species is not native to the U.S. and data were not adequate for calculation of a 96-hour LC_{50}.

[4] Pending the result of environmental fate field studies, a study on dimethoxon may be required.

[5] All data must be submitted within 36 months (due 4/86).

Table A
GENERIC DATA REQUIREM[illegible] FOR DIMETHOATE

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must A[illegible]nal Data be Submitted under FIFRA Section 3(c)(2)(B)?[7]
158.145 Wildlife and Aquatic Organisms (continued)					
72-2 - Acute LC50 Freshwater Invertebrates	1) TGAI, dimethoxon[6]	A,B,G,H,I	1) Yes	1) GS0088013 005010360 GS0088001 005009242	1) No
	2) (Unique formulation)	G	2) No		2) Yes[1]
72-3 - Acute LC50 Estuarine and Marine Organisms	Reserved[2], dimethoxon[6]				
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	Reserved[3], dimethoxon[6]		Partial[4]	GS0088005	No[3]
72-5 - Fish - Life-Cycle	Reserved[5], dimethoxon[6]				
72-6 - Aquatic Organism Accumulation	Reserved[5], dimethoxon[6]				
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	Reserved (unique Formulation)[5]				

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[1] The emulsifiable concentrate formulation used on pine forests is to be tested. The preferred test species is the stonefly, Pteronarcys californica, to provide a comparison with existing data for technical dimethoate with this species.

[2] These studies may be required for field corn, sorghum, cotton, citrus, soybean, and wheat registrations, pending environmental fate data, to evaluate hazard.

[3] These data would be required to assess the hazard of potential chronic exposure, if any, of aquatic organisms to dimethoate. Product use information, as stated in above notes, and environmental fate data are required to evaluate the extent of such exposure.

[4] The aquatic invertebrate life-cycle study cited is acceptable for hazard evaluation and may meet the intent of Subdivision E (10/1982) on a case-by-case basis should this type of study be needed for hazard evaluation.

[5] While these studies are not required at present, results of outstanding ecological effects and/or environmental fate data (including potential monitoring study(s)) could present a need for one or more of these studies to complete a hazard assessment in the future.

[6] Pending the result of environmental fate field studies, a study on dimethoxon may be required.

[7] All data must be submitted within 36 months (due 4/86).

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must A[illegible]tional Data [illegible]mitted under Section 3(c)(2)(B)?5/
Section 158.155 Nontarget Insects					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD50	TGAI	A,B,H	Yes	000026489(h) 000036935 000059971 005001991	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B,H	Partial	000045046 000060625 000060628 005000837	Yes 1/
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	B2/	Yes	000045046 000060628 005000837	No
141-4 - Honey bee subacute feeding study [Reserved]	Reserved3/				
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects [Reserved]	Reserved4/				
142-2 - Aquatic insect life-cycle study [Reserved]	Reserved4/				
142-3 - Simulated or actual Field testing for aquatic insects [Reserved]	Reserved4/				
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES: [Reserved]	Reserved4/				

1/ To support 24(c) registrations issued by the State of Arizona allowing dimethoate to be applied on citrus for the control of thrips, during the bloom period from one hour after sunset to three hours before sunrise, data are required showing that residues remaining on citrus blooms from such applications will not result in extensive bee mortality.

2/ to be cited only for products intended for foliar application to seed alfalfa.

3/ Reserved pending development of test methodology.

4/ Reserved pending decision as to whether these data requirements should be established.

5/ All data must be submitted within 36 months (due 4/86).

Table A

GENERIC DATA REQUIREMENTS FOR DIMETHOATE

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[5]
Section 158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A,B,G	No		Yes[1]
132-1 - Soil Dissipation	TEP	A,B,G	No		No[2]
132-3 - Dermal Exposure	TEP	A[3]	No		Yes[4]
133-4 - Inhalation Exposure	TEP	A[3]	No		Yes[4]

1/ For each crop, the registrant must propose an acceptable reentry interval; this proposed interval may be based on any of the following: (a) the longest (most restrictive) existing reentry intervals; (b) data on dissipation of foliar residues (decline curve), on human exposure to those residues, and on the inherent toxicity of the chemical; (c) determination of that time beyond which there are no detectable foliar residues (under climatic conditions) in the area where the chemical will be applied. Either the longest (most restrictive) reentry interval is acceptable, or the exposure data and a dislodgeable residue curve, together with the inherent toxicity of the chemical, may be used to establish an appropriate interval for activities that result in foliar contact. The longest (most restrictive) reentry intervals should be listed by crop. A decline curve of foliar residues of dimethoate and its oxygen analog is needed if registrant does not accept the longest reentry interval. Existing reentry levels have been stated in Part D, Regulatory Rationale, subpart 5 of this document.

2/ These data are not needed because the use pattern does not involve worker contact with soil.

3/ These data are required to support the air blast method of application.

4/ These studies were to be completed by 5/83 to satisfy the terms of the Position Document 4 and the 3(c(2)(B) letter (or Data Call In Notice); the Agency has received them and is reviewing them.

5/ All data must be submitted within 36 months (due 4/86).

Table B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DIMETHOATE

Data Requirement	Composition	Does [illegible] ve Data to Sat[illegible]y This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data 'e Submitted under FIFRA Section 3(c)(2)(B)?[4]
Section 158.120 Product Chemistry				
61-1 - Identity of Ingredients	MP	Partial[1]	000071499 [4787-7](b)	Yes
61-2 - Statement of Composition	MP	Partial[2]	0000075600 [241-218](a) 0000071499 [4787-7](b) 0000075618 [33660-12]	Yes
61-3 - Discussion of Formation of	MP	Partial[1]	000071499 [4787-7](b)	Yes
	- Impurities	Partial[3]	000075657 [241-218](a) 000075658 [241-218](a) 000075652 [241-218](a)	Yes
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	Partial[1]	000083039 [4787-7](b) 000071503 [4787-7](b)	Yes
62-2 - Certification of Limits	MP	Partial[1]	000071499 [4787-7](b)	Yes
62-3 - Analytical Methods for Enforcement of Limits	MP - Active Ingredient	Yes	000077481(a) 000075616(g) 000083037 [4787-7](b)	No
	- Impurities	Partial[1]	000083039 [4787-7](b)	Yes

1/ Satisfactory data have been submitted for the products(s) indicated. Data must be submitted for all other products.

2/ Manufacturing process data need not be submitted for 241-218, 4727-7 and 33660-12. A description of beginning materials is required for all MPs.

3/ The methylamide group of dimethoate is nitrosatable, and nitrosmines may form on storage is nitrosating agents are present in the packaging materials. Satisfactory data have been submitted for the products indicated that nitrates and nitrites are not present in their containers. All registrants should submit evidence that their product containers are free of nitrosating agents.

4/ All data must be submitted within 6 months (due 9/30/83).

Table B.
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DIMETHOATE

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[2]
Section 158.120 Product Chemistry				
Physical and Chemical Characteristics:				
63-2 - Color	MP	Yes	00071505(b); 000075618 00077481(a); 00075612(c) 00075570(d)	No
63-3 - Physical state	MP	Yes	00071505(b); 000075618 00077481(a); 000075612(c) 00075570(d)	No
63-4 - Odor	MP	Yes	00071505(b); 00075618 00077481(a); 000075612(c)	No
63-7 - Density, Bulk Density, or Specific Gravity	MP	Partial[1]	CSF [241-231](a)	Yes

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[1] Satisfactory data have been submitted for the product(s) indicated. Data must be submitted for all other products.

[2] All data must be submitted within 6 months (due 9/30/83).

Table B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DIMETHOATE

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[2]
Section 158.120 Product Chemistry (continued)				
64-12- pH	Each MUP	Partial[1]	000071505 [4787-7](b) 000075612 [2749-46](c)	Yes
64-14- Oxidizing or reducing action	Each MUP	Yes	00071505(b)	No

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[1] Satisfactory data have been submitted for the product(s) indicated. Data must be submitted for all other products.

[2] All data must be submitted within 6 months (due 9/30/83).

Table B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DIMETHOATE

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?[5]
Section 158.24 Product Chemistry (continued)				
63-15- Flammability	MP	Yes	000071505(b) 000075618 000077481(a) 000075612(c)	No
63-16- Explodability	MP	Yes	000071505(b) 000075612 (c)	No
63-17- Storage Stability	MP	Partial[1]	000071505[4787-7](b)	Yes
63-18- Viscosity	MP	No	-	Yes[2]
63-19- Miscibility	MP	No	000071505(b)	Yes[3]
63-20- Corrosion	MP	Yes	000075612(c)	No
Other Requirements				
64-1 Submittal of Samples			Reserved [4]	

[1] Satisfactory data have been submitted for the product(s) indicated. Data must be submitted for all other products.
[2] These data are required only for liquid MP's.
[3] These data are required only for emulsifiable liquid MP's.
[4] The Agency will require a sample later if need arises.
[5] All data must be submitted within 6 months (due 9/30/83).

Table B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DIMETHOATE

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted under FIFRA Section 3(c)(2)(B)?1/
Section 158.135 Toxicology				
ACUTE TESTING:				
81-1 - Oral LD50 - Rat	MP	Yes	000055377(d); 000051674(a); 000055371(d); 000049330; 000073757(f); 000073440(a); 000037597; 000044988(a); 000043996; 000071569(b); 000071504(b); 000051677(a); 000014982(a)	No
81-2 - Dermal LD50	MP	Yes	000051674(a); 000049330	No
81-3 - Inhalation LC50 - Rat	MP	Yes	000060719(f)	No
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	000027098(i)	No
81-5 - Primary Dermal Irritation	MP	Yes	000069156(f)	No
81-6 - Dermal Sensitization	MP	No	-	Yes

1/ All data must be submitted within 6 months (due 9/30/83).

V. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA UNDER FIFRA § 3(c)(2)(B)

Note: This section applies only to manufacturing use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B) EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than 6 months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under § 3(c)(2)(B)."

In some cases Table B may note that EPA already possesses some or all of the product-specific data needed to evaluate your product; if that is the case, you must comply with FIFRA Section 3(c)(1)(D). See Section III of this guidance document.

VI. LABELING AND PACKAGING INFORMATION

Note: This section applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you must submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.1], as indicated by the following paragraphs of this section of the guidance document. The labeling must be submitted within 6 months of your receipt of this guidance document.

If owners of currently registered products fail to submit revised labeling and packaging information complying with this section, EPA will issue a notice of intent to cancel the registration under FIFRA § 6(b)(1).

A. Label Contents

40 CFR Section 162.10 (Appendix VI-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix VI-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix VI-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net content must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix VI-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix VI-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix VI-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix VI-1. [40 CFR §162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various sized labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word As Required Minimum Type Size All Capitals	"Keep out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix VI-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix VI-1. [40 CFR §162.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned toxicity Category I on the basis of oral, inhalation or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix VI-1. (40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix VI-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or back) Panel for Additional Precautionary Statement" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix VI-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix VI-1. [40 CFR §162.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix VI-1. [40 CFR §162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. See Appendix VI-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix VI-3. The requirement is based on the results of the flash point determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flash point greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8 (c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii).

      ii. There is no flash back; and

      iii. The flash point of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazard of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." Appendix VI-1 [40 CFR §162.10(l)(2)(ii)]

Item 10A. STORAGE & DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix VI-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix VI-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

VII. Instructions for Submission

All applications prepared in response to this Notice should be addressed as follows:

William H. Miller
Phone No. (703) 557-2600
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, DC 20460

A. For each manufacturing-use product for which continued registration is desired:

1. Within 90 days from receipt of this document you must submit the "FIFRA Section (3)(c)(2)(B) Summary Sheet." Refer to Appendix IV-2(a) with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. "Application for Amended Pesticide Registration" (EPA Form 8570-1).

   b. "Confidential Statement of Formula" (EPA Form 8570-4).

   c. "Data Compensation Statement: Reregistration." Refer to Appendix III-1(a).

   d. Product Specific Data Report (Appendix III-2).

   e. Two copies of any required product-specific data.

   f. Two copies of draft labeling, including the label and associated brochures. If the current labeling conforms to the requirements of this guidance document and the results of the short term data, the registrant can submit such labeling. Otherwise, the labeling should be in draft form. The draft labeling should be either type-written text on 8-1/2 x 11 inch paper or a mock-up of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front and side panels, and the intended type sizes of the text.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrants.

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

B. For each affected product for which continued registration is desired, within 90 days from receipt of this document submit:

1. The "FIFRA Section 3 (c)(2)(B) Summary Sheet" (Appendix IV-2) with appropriate attachments, and

2. The "Data Compensation Statement: Reregistration." Refer to Appendix III-1(b).

Appendix III-1(a)

DATA COMPENSATION STATEMENT: REREGISTRATION (MUPs)

EPA Reg. No.: ______________________________

Product Name: ______________________________

Applicant's Name & Address: ______________________________
____
____

Date of application for reregistration: ______________________________

Registration Standard for products containing: ______________________________

Date Reregistration Guidance Document Issued: ______________________________

In connection with applicant's application for reregistration under the Guidance Document identified above:

(A) Applicant offers to pay compensation to other persons to the extent required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

(B) Applicant understands and acknowledges that if EPA approves the application, the approval will be based solely on EPA's consideration of:

(1) All the generic data which, according to the Guidance Document identified above, were found relevant to EPA's evaluation of the registrability of applicant's product; and

(2) The product-specific data listed on the form entitled "Product-Specific Data Report" which is part of this application; and

(3) Applicant states that offers to pay compensation have been furnished to the persons and in the form specified by the Guidance Document identified above.

Dated: ______________________________

Name of registrant's
authorized representative: ______________________________
(signature)

____
(typed)

DATA COMPENSATION STATEMENT: REREGISTRATION (End-Use Products)

EPA Reg. No.: ____________________

Product Name: ____________________

Applicant's Name & Address: ____________________
____
____

Date of application for reregistration: ____________________

Registration Standard for products containing: ____________________

Date registration Guidance Document Issued: ____________________

Registrant offers to pay compensation to other persons for the data listed in Table A to the extent required by sections 3(c)(1)(D) and 3 (c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registrant has furnished offers to pay compensation to the persons identified in Table A and in the form specified by the Guidance Document.

Dated: ____________________

Name of registrant's
authorized representative: ____________________
(signature)

____
(typed)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.________ Guidance Document for________________________________

Date:________________________

		Test not required for my product listed above (check below)	I am complying with Data Requirements by		(For EPA Use Only) Accession Numbers Assigned
Registration Guideline No.	Name of Test		Citing MRID #	Submitting Data (attached)	
163.61-3	Product identity and disclosure of ingredients				
-4	Description of manufacturing process				
-5	Discussion on formation of unintentional ingredients				
-6	Declaration and certification of ingredient limits				
-7	Product analytical methods and data				
163.61-8(1)	Color				
-8(2)	Odor				
-8(3)	Melting Point				
-8(4)	Solubility				
-8(5)	Stability				
-8(6)	Octanol/water partition coefficient				
-8(7)	Physical state				
-8(8)	Density or specific gravity				
-8(9)	Boiling point				
-8(10)	Vapor pressure				
-8(11)	pH				
-8(12)	Storage stability				
-8(13)	Flammability				
-8(14)	Oxidizing or reducing action				
-8(15)	Explosiveness				
-8(16)	Miscibility				
-8(17)	Viscosity				
-8(18)	Corrosion characteristics				
-8(19)	Dielectric breakdown voltage				
163.71-5(1)	Cage or pen field test				
-5(2)	Full scale field test				
163.72-1	Fish acute LC_{50}, rainbow trout and bluegill				
163.72-2	Acute toxicity to aquatic invertebrates				
-3	Acute toxicity to estuarine and marine organisms				
-6(a)(1)	Short term simulated field test				
-6(a)(2)	Long term simulated field test				
163.81-1	Acute oral toxicity				
-2	Acute dermal toxicity				
-3	Acute inhalation toxicity				
-4	Primary eye irritation				
-5	Primary dermal irritation				
-6	Dermal sensitization				

Standard Abbreviations, Codes and Data Compensation Footnotes, Used in the Following Tables

MP = Manufacturing Use Product

TGAI = Technical Grade of Active Ingredient

CSF= Confidential Statement of Formula

PAIRA = Pure Active Ingredient, Radio-Labeled

TEP = Typical End-Use Product

MRID = Master Record Identity
PAI = Pure Active Ingredient

Use Pattern Codes:

A: Terrestrial Food Crop
B: Terrestrial Nonfood
G: Forestry
H: Domestic Outdoor
I: Indoor

Data Compensation Footnotes

a. Studies submitted by American Cyanamid. These studies may be compensable.
b. Studies submitted by Cheminova. These studies may be compensable.
c. Studies submitted by Aceto. These studies may be compensable.
d. Studies submitted by Fisons. These studies may be compensable.
e. Studies submitted by Thompson-Hayward Chemical Co. These studies may be compensable.
f. Studies submitted by FMC. These studies may be compensable.
g. Studies submitted by Intrachem SA. These studies may be compensable.
h. Studies submitted by Monsanto. These studies may be compensable.
i. Studies submitted by Industria Prodotti Chimici, S.p.a. These studies may be compensable.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

  (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

  (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

  (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

  (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn

followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
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000033896 Bohn, W.R. (1962?) The Disappearance of Dimethoate from Soil. (Unpublished study received May 6, 1965 under 241-94; submitted by American Cyanamid Co., Princeton, N.J.; CDL:001779-C)

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000044983 American Cyanamid Company (1960) Metabolism Summary. (Unpublished study received on unknown date under unknown admin. no.; CDL: 109334-A)

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000045046 Johansen, C.; Mayer, D.; Madsen, R.; et al. (1975) Bee Research Investigations, 1975. (Unpublished study received Dec 20, 1976 under 100-EX-53; prepared by Washington State Univ., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095990-E)

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OFFICE OF PESTICIDE PROGRAMS
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FIFRA §3(C)(2)(B) SUMMARY SHEET

EPA Registration No.:________________________________
Product Name:______________________________________
Applicant's Name:___________________________________
Date Guidance Document Issued:_________________________

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(c)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

1. ☐ I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

2. ☐ I have entered into an agreement with one or more other registrants under FIFRA § 3(c)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by (name of other registrant).

3. ☐ I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

4. ☐ I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

5. ☐ I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

Dated:___________________

Registrant's authorized representative:

____
(signature)

____
(typed)

Appendix IV-3

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(TO QUALIFY, CERTIFY ALL FOUR ITEMS)

(1) I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document dated ____________ to submit data concerning the active ingredient ____________________________________:

Name of Firm	EPA Company Number

(This firm or group of firms is referred to below as "my firm".)

(2) My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

(3) My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Firm	Date of Offer

However, none of those firm(s) accepted my offer.

(4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

Dated:__________________ ________________________________
(Signature)

____
(Typed)

cc: A copy of the offer(s) is attached.

cacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:

(1) The data the applicant has submitted to EPA under paragraph (b) of this section;

(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and

(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.

(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:

(1) A notification of the applicant's intent to apply for registration, including the proposed product name;

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);

(3) An identification of the item(s) of data to which the offer applies;

(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(5) The applicant's name, address, and telephone number.

(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27953, May 11, 1979]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person [illegible] whom the pesticide was produc[illegible]ears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number prec[illegible]ed by the phrase "EPA Est.", of

final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas [illegible]icological hazard including haz[illegible] children, environmental hazard, [illegible] physical or chemical hazard fall into two groups those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD₅₀	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC₅₀	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD₅₀	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive, corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days, irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word[illegible] associated with a higher Toxicity [illegible]ory is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Required signal word, all capitals	"Keep out of reach of Children"
	Points	Points
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects.
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statem[illegible] are required stating the nat[illegible] the hazard and the appropri[illegible] precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

(A) PRESSURIZED CONTAINERS

Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.

(B) NONPRESSURIZED CONTAINERS

Flash point	*Required text*
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be

STORAGE INSTRUCTIONS FOR PESTICIDES

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage temperature, potential for breakage of glass, crushing or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

§ 162.11 Criteria for determinations of unreasonable adverse effects.

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a de-

TABLE D
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.

TABLE E

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		

TABLE F-1

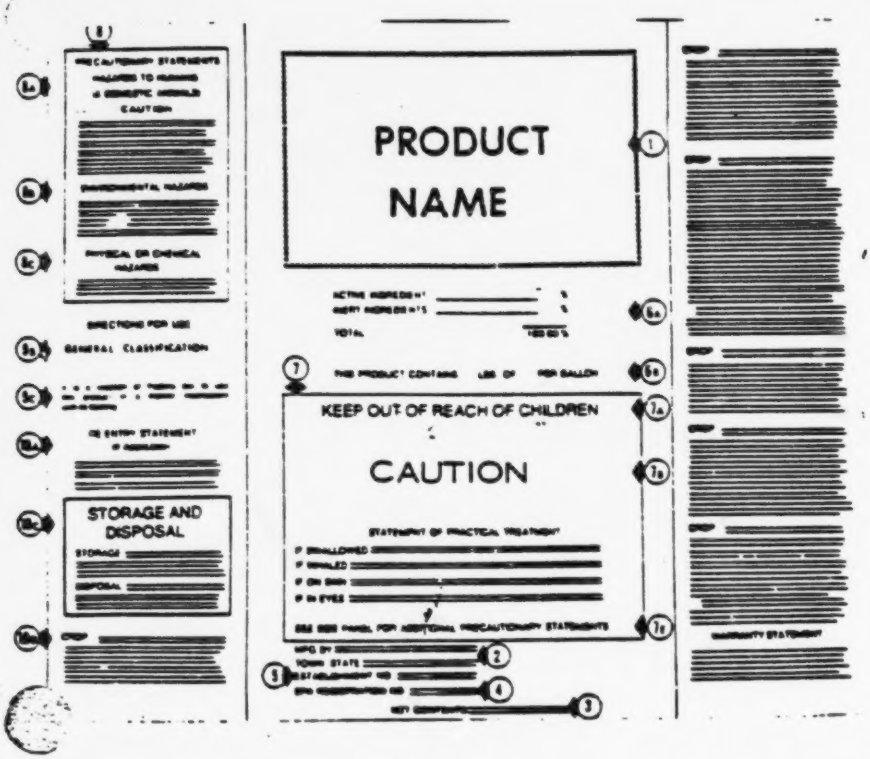
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	

TABLE F-2

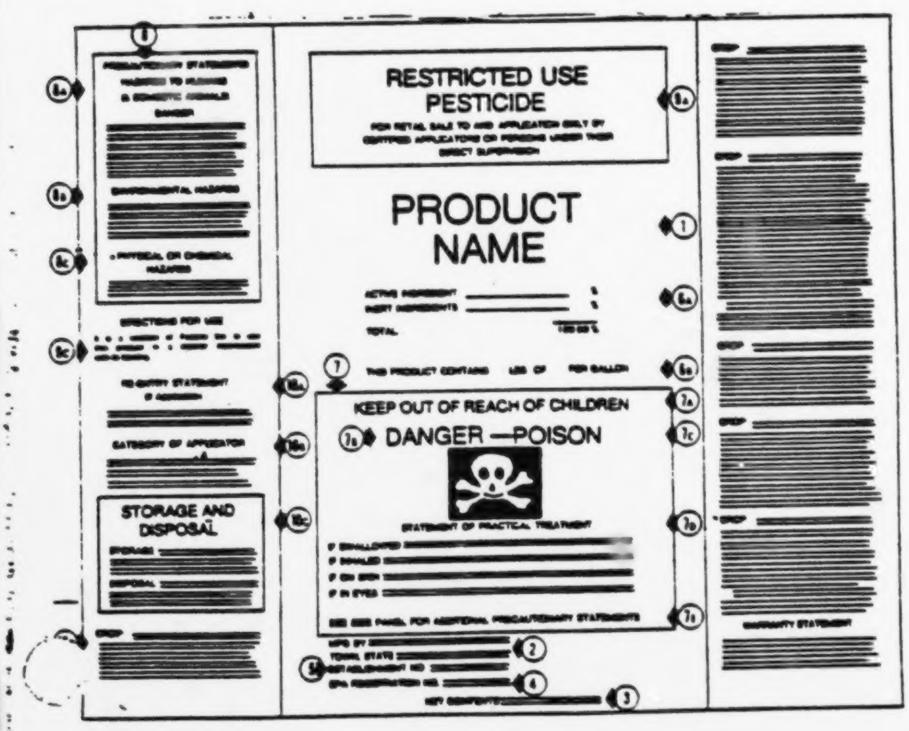
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be grouped together, and preferably blocked. Heading must be same type size as child hazard warning.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

APPENDIX VI-2

SAMPLE LABELS


PRODUCT NAME
KEEP OUT OF REACH OF CHILDREN
CAUTION
STORAGE AND DISPOSAL
STATEMENT OF PRACTICAL TREATMENT
DIRECTIONS FOR USE
GENERAL CLASSIFICATION
WARRANTY STATEMENT
1
2
3
4
5
7

General Use Pesticide


RESTRICTED USE PESTICIDE
PRODUCT NAME
KEEP OUT OF REACH OF CHILDREN
DANGER —POISON
STORAGE AND DISPOSAL
STATEMENT OF PRACTICAL TREATMENT
DIRECTIONS FOR USE
CATEGORY OF APPLICATOR
WARRANTY STATEMENT
1
2
3
4
5
7

Restricted Use Pesticide

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flash point at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.